

needle from being re-extended to re-expose the needle.

20. (Previously Added) The method of claim 5 wherein the step of displacing comprises actuating an actuator such that a biasing element displaces the needle.

REMARKS

In an Official Action dated December 3, 2002, the pending claims were rejected under §102 as anticipated by Yoon '053, and nonstatutory double patenting. In addition, claims 17 and 19 were rejected under §112 as lacking antecedent basis for a term "the shielded position". Applicants believe that the enclosed terminal disclaimer overcomes the double patenting rejection. In addition, although Applicants believe that the claims are clear and definite, claims 2 and 5 (from which claims 17 and 19 depend) have been amended to specifically recite the term "shielded position". In light of the amendment, Applicants believe that the §112 rejection is overcome. Accordingly, the discussion below focuses on the §102 rejection based on Yoon '053.

Yoon '053 is directed to safety needle instruments for penetrating a wall of an anatomical cavity, such as for piercing the patient's abdominal wall during laproscopic surgery. The device is designed so that once the needle pierces through the anatomical wall, a safety element springs forward to prevent the needle from piercing any internal organs. In contrast, Applicants' device operates by retracting the needle into a shield after use to preventing inadvertent needle sticks. This difference is reflected in the claims and is discussed in more detail below.

Yoon '053 has numerous embodiments, and the Official Action refers to the fourth embodiment illustrated in Fig. 11.

The device 320 in Fig. 11 of Yoon '053 includes a needle 324 and a safety shield 371. The rearward end of the needle 324 forms a flange 332 that is

biased forwardly by a spring 356. Col. 11 lines 26-27. A flange 334 forms a lip that prevents the spring 356 from forcing the needle 324 beyond a predetermined position.

The safety shield is mounted over the needle 324 to slide over the needle 324. A second spring 354 biases the shield forwardly over the needle. Col. 11 lines 32-35. A locking mechanism 374 holds the shield 371 in a rearward position in which the tip of the needle is exposed.

To use the Yoon '053 device, the user manually pulls on a handle 362 to pull the safety shield rearwardly to uncover the sharpened tip of the needle. As the user pulls on the handle the second spring 354 is compressed. The handle is pulled until a latch 386 engages a flange 352 on the shield 371, so that the latch locks the shield in place against the bias of the second spring 354. Col. 11 line 55 - col. 12 line 2. After the shield is locked in place, the device can be inserted into a patient.

During penetration of the patient's anatomical cavity wall, the needle 324 moves rearwardly against the bias of the spring 356. After the needle pierces through the anatomical wall and into the anatomical cavity the wall creates less rearward force against the needle. so that the needle begins to move forwardly from the force of the first spring 356. As the needle moves forwardly, the flange 332 on the needle engages trigger 394, pivoting the trigger counter-clockwise. The pivoting trigger 394 pivots the latch 384 away from the flange 352 attached to the safety shield, thereby releasing the shield so that the second spring 354 forces the shield forwardly over the needle. Col. 12 lines 5-26. In this way, the safety shield 371 is automatically advanced over top of the needle 324 after the needle pierces the anatomical wall thereby preventing the needle from piercing the internal organs.

In short, the Yoon '053 device has a first spring that biases the needle forwardly, and a second spring 354 that biases the shield forward. The needle 324

does not retract; it is only pushed rearwardly against the bias of the first spring 356 when the needle is pushed through the anatomical wall.

In contrast, Applicants' device is a safety device having a needle 65 and a shield 30 that sheaths the needle. The needle and shield can be inserted into the patient, and the needle can be retracted so that the sharpened tip of the needle is retracted rearwardly into the shield for piercing a patient. The needle can be retracted into the shield either before the device is withdrawn from the patient or after it is withdrawn.

The needle is held in place against the bias of a spring 60 by a needle retainer 42. The needle is released for retraction by pressing down on a release button 43. After the needle is released for retraction, the spring propels the needle rearwardly so that the needle tip is shielded within the shield.

With respect to claim 1, claim 1 recites :

A medical device, comprising:

- a hollow housing;

- a needle having a sharpened tip projecting forwardly from the housing;

- a biasing element biasing the needle rearwardly;

- a needle retainer releasably retaining the needle against the rearward bias of the biasing element;

- a flexible shield fixedly attached to the housing, projecting forwardly from the housing;

- the shield having a forward edge and being configured for insertion into a patient;

- the shield sheathing the needle such that in a projecting position, the sharpened tip of the needle projects beyond the forward edge of the shield, and in a retracted position the sharpened tip is enclosed within the shield;

wherein upon actuation of the needle retainer, the biasing element displaces

the needle rearwardly so that the sharpened tip of the needle is enclosed within the shield, wherein the shield is substantially puncture resistant wherein the axial force required to buckle the shield is less than the force necessary to puncture the shield with the needle to prevent inadvertent contact with the contaminated needle.

Yoon '053 does not teach or suggest numerous features of claim 1. For instance, Yoon '053 does not teach a biasing element biasing the needle rearwardly. Yoon '053 discloses two springs 354 and 356, but neither bias the needle rearwardly. The first spring biases the needle forwardly to actuate release of the shield after the needle pierces the anatomical wall; the second spring biases the shield forwardly.

Another difference is that Yoon '053 does not teach or suggest a needle retainer that releasably retains the needle against the bias of the biasing element. Yoon '053 does not have a needle retainer because Yoon '053 does not release the needle for retraction. It releases the shield.

Another difference is that Yoon '053 does not teach a flexible shield fixedly attached to the housing. In fact, Yoon '053 would not work with a shield fixed to the housing. As discussed above, the whole operation of Yoon '053 is premised on having the shield not be fixed to the housing so that the shield can be propelled forward over the needle.

In light of all of the differences between structure and function of Yoon '053 and claim 1, Yoon does not anticipate claim 1. Accordingly, Applicants request that the Examiner reconsider the rejection of claim 1 and dependent claims 13-16.

With respect to claim 2, Yoon '053 does not teach the step of retracting the needle into the shield, as discussed above. A further difference is that Yoon '053 does not teach or suggest infusing fluid through the shielded needle into the patient. In light of these differences between Yoon '053 and claim 2, Yoon '053

does not anticipate claim 2 and dependent claims 17-18.

With respect to claim 5, Yoon '053 does not teach or suggest the step of displacing the needle rearwardly so that the needle is disposed within the shield, as discussed above. A further difference is that Yoon '053 does not teach or suggest transferring blood or plasma through the shielded needle. In light of these differences between Yoon '053 and claim 5, Yoon '053 does not anticipate claim 5 and dependent claims 19-20.


Claim 8 includes features that are similar to claim 1. Accordingly, the differences discussed above between claim 1 and Yoon '053 are similar to the differences between Yoon '053 and claim 8. For instance, claim 8 recites a biasing element biasing the needle rearwardly, a needle retainer releasably retaining the needle against the bias of the biasing element and a shield fixedly attached to the housing. Yoon '053 does not teach or suggest any of these features. Accordingly, Yoon '053 does not anticipate claim 8 and dependent claims 9-12.

In light of the foregoing, Applicant believes that this application is in form for allowance. The Examiner is encouraged to contact Applicant's undersigned attorney if the Examiner believes that issues remain regarding the allowability of this application.

Respectfully submitted,

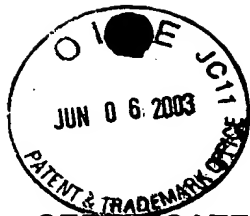
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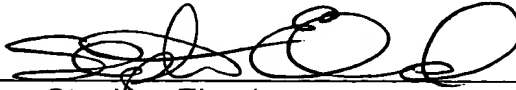
Patent Application No. 09/837,539

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this Response and accompanying papers are being deposited on June 3, 2003 with the United States Postal Service as first-class mail in an envelope properly addressed to COMMISSIONER OF PATENTS AND TRADEMARKS, Washington, DC 20231

June 3, 2003

Date of Certificate




Stephen Eland

Petition for Extension Under 37 CFR §1.136(a)

Applicant's undersigned Attorney hereby petitions for an extension of time of THREE months beyond the time period set in the last office communication. The proper fee is enclosed as identified in the enclosed Fee Transmittal form.

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